JUL 1 9 2000

K000869

510K, Summary

510(K) Pre-Market Notification
Powered Three-Wheel Vehicle

March 10, 2000

This summary and overview for 510(K), safety and effectiveness information, is being submitted in accordance with the requirements of 21 CFR 807.87, manufacturing and distribution, and elements for submitting a 510K, for a "three-wheeled vehicle" as defined under 21 CFR 890.3800

The assigned 510(K) number is:

Name of Device: Electric-Powered Three-Wheel Vehicle
Proprietary Name: LA Personal Scooter
Common Name: LA Scooter
Classification Name: Electric-Powered Three-Wheel Scooter
Submitted by Gary Darling
Principle contact: Gary Darling
Engineering contact: Pat Turner

- Legally marketed device to which our company is claiming equivalence: PaceSaver, by Leisure-Lift, Inc., 1800 Merriam Lane, (P.O. Box 6176) Kansas City, KS 66106. PaceSaver is the chosen predicated scooter, based on their PlusIII, Eclipse and Junior series. See Attachment 2-A.

- Description of device: An electric three-wheel vehicle with cushioned seat, a trans-axle motor drive with variable speed – forward & reverse speed controller. Extra heavy construction for heavier passengers. Fully assembled. More information provided in Attachment 2-B.

- Intended use of our device: The LA Personal Scooter offers mobility for people who are physically challenged. It can be used indoors and outdoors for a user who is lacking full common use of lower body extremities. The duration can be both long-term and short-term from numerous physical causes, ranging from difficult pregnancy to broken bones to spinal cord injury. The Personal Scooter is intended for home, lawn, sidewalk and normal and handicap pedestrian traffic not exceeding a slope of 7-degree angle.

- Description of device: The LA Personal Scooter provides mobility by incorporating throttle grips located on a steering column, which electrically motivates a motor and trans-axle that propels the device. Control power is supplied by electronics located on the steering column. The control electronics incorporate safety features such as speed control, direction indicators, battery life indicator, low-battery warning indicator, power on & power off indicator, and keyed electric power switch. Motor power is supplied by a PWM (pulse-width modulator). The PWM features run-inhibit (scooter won't move or accelerate when being charged by external charger). Other safety features include a pressure power switch inside the cushion. The scooter will not run or accelerate if the rider isn't seated. More information provided in Attachment 2-B.

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- Summary of technological characteristics of our device compared to the predicated device: A list of characteristics is found in Attachments 2-A & 2-B.

- Brief description of non-clinical tests and how their results support a determination of substantial equivalence: Tests involved using the predicated device alongside the LA Scooter and subjecting both units to identical examinations. Description can be found in Attachment 1.

- Labeling: Labels, decals, signs and plates. All items that will be used on the scooter, in the Owner's manual, and on any other related literature. A facsimile of each item can be found with an explanation of its intended purpose in Attachment 2-B.

- Classification of Device: Class 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Mr. Gary Darling
Assembled Products Corporation
115 East Linden
Rogers, Arkansas 72756

Re: K000869
Trade Name: LA 300 Personal Scooter
Regulatory Class: II
Product Code: INI
Dated: June 20, 2000
Received: June 23, 2000

Dear Mr. Darling:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000869

Device Name: LA Personal Scooter

Indications For Use:

The LA 300 Personal Scooter is intended to offer mobility for people who are physically challenged (handicapped). It can be used indoors and outdoors for a user who is lacking full common use of lower body extremities. The duration of use can be both short-term, long-term and chronic because of numerous physical causes, ranging from difficult pregnancy to broken bones to spinal cord injury. The Personal Scooter is intended for home, lawn, sidewalk as well as normal and handicap pedestrian traffic not exceeding a slope of 7-degrees angle.

6-21-00

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000869

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)